

Talking Points
April 3, 2021
11am call with Emergent Biosolutions CEO

Attendees: Bob Kramer, CEO Emergent Biosolutions
Joaquin, Kathy , Remo

Kathy to open meeting

- Bob, we appreciate you being with us here on a Saturday after a long week
- We have Remo with us, plus I want to introduce Joaquin Duato who is Vice Chair of J&J, with responsibility for about 2/3 of J&J's business including our Pharmaceuticals and Consumer Health businesses worldwide, plus my team and other functions
- As we discussed on Thursday evening, this partnership is critically important to us and Joaquin wanted to spend some time with us
- -Joaquin, over to you...

Joaquin

- Bob, it's a pleasure to meet you
- I want to start by thanking you and all your team at Emergent
- You are one of our first partners in our goal to have 1B vaccines this year, and that means a lot
- I know from Kathy and Remo that you feel like I do - how unusual things are right now – we have a microscope on everything
- We have the opportunity together to truly change trajectory of COVID
- Our vaccine designed to be the workhorse of the pandemic, and
- Appreciate partnership and everything you have done over the past year
- At the same time, we are in a very difficult moment...
- Every small thing is amplified thousands of times over
- Things that are not noticed in normal times are now huge problems in today's world
- FDA has some real concerns and we need to put the full force of both of our companies' expertise to bring them confidence we can successfully move forward.
- You are CRITICAL to the future of our vaccine, and as such we have to do everything and frankly anything we need to do, to support your EUA
- This means we have to work together on approaches that we would not do in normal times...
- Because we also want this partnership to be there also in normal times
- Our vaccine business has an important future, and we want to sustain longer term partnerships around the world
- But right now everything comes down to how we move forward together this week and support your approval.
- Would like to hear your thoughts....

Bob
-xxx

Kathy – at right moment.

- Everything comes down to the next week and how we collectively give FDA the right level of assurance
- We know it is not easy to start-up a new process yet we also are expected to have a high level of compliance every minute of everyday – from every member of the workforce
- Bob, unfortunately since we spoke just two days ago, we have continued to get signals – sometimes more than signals – that FDA is very unhappy. As I shared, they were very strong in the meeting last week. And since we spoke on Thursday, they have expressed specific concerns about us continuing even at risk to fill your ds into vials.
- I understand FDA is speaking with your team on Monday.
- At the same time, you and we are submitting our investigation report.
- We need your support to make sure your team understands there are things we will need to agree together in this unusual time that include increased roles for us in supervision, direction and support
- Our teams are working together for a few hours this afternoon on these roles/responsibilities. We need that outcome to be alignment on the base case we are going to submit. And I am happy to circle back with you and team after that meeting.
- We need to put all our force to ensure that outcome is enough.
- But if it is not enough, we will need to do whatever it takes to get your EUA over the line
- I can assure you that our goal is your goal – the long-term sustainability of this process and your site as a key partner.
- I would greatly appreciate that your team understands your commitment and works with us in this extraordinary situation.
- Remo, any thoughts?

Remo

- We have resources and expertise that can assist you and your new hires coming up the curve much faster
- Will need to be holistic and cover all areas related to our product.
- [commentary on key areas of attention]

Kathy

- My ask is that if we have any question after today's working session, we get together later today (and maybe tomorrow) to review.
- I want to thank you and your team – not an easy to ask everyone to work over Easter. Remo and Robin have been extraordinary about motivating their teams, and I know the same for you Bob.

Joaquin

- any closing thoughts?